

Clinical trials of autologous bone marrow stem cells

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1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
autologous bone marrow stem cells vs control			
ASTAMi (Lunde) , 2006 n=50/50 follow-up: 6 months	intracoronary injection of autologous mononuclear BMC (stem cells $0.68 \cdot 10^8$) <i>versus</i> <i>control(Heparanizedplasma)</i>	patients with acute ST-elevation myocardial infarction of the anterior wall treated with percutaneous coronary intervention	parallel group open
BOOSt (Meyer) , 2004 n=30/30 follow-up: 6 months	stem cells mean $2.46 \cdot 10^9$ <i>versus</i> <i>control(Heparanisedplasma)</i>	successful percutaneous coronary intervention (PCI) for acute ST-segment elevation myocardial infarction	parallel group open
Chen , 2004 n=NA follow-up: 6 months	-	-	
Huang , 2006 n=20/20 follow-up: 6 months	intracoronary transplantation of autologous BM-MNC via a micro-catheter right after PCI (stem cells mean $1.8 \cdot 10^8$) <i>versus</i> <i>placebo(Heparanisedsaline)</i>	patients with first onset of acute inferior-wall myocardial infarction aged $< \text{or} = 75$, treated with emergent percutaneous coronary intervention	parallel group open
Karpov , 2005 n=10/10 follow-up: 6 months	intracoronary injection of bone marrow mononuclear cells (stem cells mean $88.5 \cdot 10^6$) <i>versus</i> <i>control</i>	patients with acute myocardial infarction.	parallel group NA
Li , 2007 n=35/23 follow-up: 6 months	autologous peripheral blood stem cell transplantation by intracoronary infusion (stem cells mean $7.25 \cdot 10^7$) <i>versus</i> <i>control</i>	patients with AMI	parallel group open
MAGIC (cell infusion) , 2004 n=10/7 follow-up:	intracoronary infusion of collected peripheral blood stem-cells <i>versus</i> <i>control</i>	patients with myocardial infarction who underwent coronary stenting for the culprit lesion of infarction	

continued...

Trial	Treatments	Patients	Trials design and methods
MAGIC Cell-3-DES (Kang) , 2006 n=25/25 follow-up: 6 months	intracoronary infusion of mobilized peripheral blood stem cells by granulocyte colony-stimulating factor (stem cells $1-2 \cdot 10^9$) <i>versus</i> <i>control</i>	patients with myocardial infarction who underwent coronary revascularization with DES for the culprit lesion	parallel group open
Meluzin HD , 2006 n=22/22 follow-up: 3 months	intracoronary mononuclear bone marrow cells (stem cells 10^8) <i>versus</i> <i>control</i> (<i>Cellsuspensionmedia</i>)	patients with a first acute myocardial infarction	parallel group open
Meluzin LD , 2006 n=22/22 follow-up: 3 months	intracoronary mononuclear bone marrow cells (stem cells 10^7) <i>versus</i> <i>control</i> (<i>Cellsuspensionmedia</i>)	patients with a first acute myocardial infarction	parallel group open
Penicka , 2007 n=14/10 follow-up: 4 months	Intracoronary injection of autologous bone marrow-derived mononuclear cells (stem cells $26.4 \cdot 10^8$) <i>versus</i> <i>control</i>	patients with large anterior acute myocardial infarction	parallel group open
Ruan , 2005 n=9/11 follow-up: 6 months	intracoronary injection of bone-marrow cell (stem cells dose NA) <i>versus</i> <i>control</i> (Diluted serum)	with acute myocardial infarction and anterior descending coronary artery occlusion proven by angiography	parallel group open
Suarez de Lezo (cell) , 2007 n=10/10 follow-up: 3 months	intracoronary infusion of autologous mononuclear bone marrow cells ($9 \cdot 10^8$) <i>versus</i> <i>control</i> (<i>Salinecontaining0.1%heparin</i>)	patients with revascularized anterior wall AMI and depressed left ventricular function (ejection fraction $<45\%$)	parallel group open
TCT-STAMI (Ge) , 2006 n=10/10 follow-up: 6 months	emergent intracoronary autologous bone marrow cell transplantation ($4 \cdot 10^7 SC$) <i>versus</i> <i>control</i>	patients admitted within 24 h after the onset of a first AMI	parallel group NA
autologous bone marrow stem cells vs placebo			
Janssens , 2006 n=33/34 follow-up: 4 months	stem cells mean $1.7 \cdot 10^8$ <i>versus</i> <i>placebo</i> (<i>Salineand5%autologousserum</i>)	patientst with successful percutaneous coronary intervention for STEMI	parallel group double blind

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Trial	Treatments	Patients	Trials design and methods
REPAIR-AMI (Schachinger) , 2006 [NCT00279175] n=95/92 follow-up: 4 months	intracoronary infusion of progenitor cells derived from bone marrow (stem cells mean $2.36 \cdot 10^8$) <i>versus</i> <i>placebo(X – vivomediaand20%autologousserum)</i>	patients with acute myocardial infarction	double blind
TIME ongoing n=NA follow-up:	autologous bone marrow-derived mononuclear cells (BMMNCs) versus placebo	patients with moderate-to-large anterior AMIs who have undergone successful percutaneous coronary intervention of the left anterior descending coronary artery and have a left ventricular (LV) ejection fraction $\leq 45\%$ by echocardiography.	Parallel groups double blind

More details and results :

- cell-based therapies for acute myocardial infarction in PCI at <http://www.trialresultscenter.org/go-Q313>

References

ASTAMI (Lunde), 2006:

Lunde K, Solheim S, Aakhus S, Arnesen H, Abdelnoor M, Egeland T, Endresen K, Ilebakk A, Mangschau A, Fjeld JG, Smith HJ, Taraldsrud E, Grgaard HK, Bjrnerheim R, Brekke M, Mller C, Hopp E, Ragnarsson A, Brinchmann JE, Forfang K Intracoronary injection of mononuclear bone marrow cells in acute myocardial infarction. *N Engl J Med* 2006;355:1199-209 [16990383] [10.1056/NEJMoa055706](https://doi.org/10.1056/NEJMoa055706)

Beitnes JO, Hopp E, Lunde K, Solheim S, Arnesen H, Brinchmann JE, Forfang K, Aakhus S Long-term results after intracoronary injection of autologous mononuclear bone marrow cells in acute myocardial infarction: the ASTAMI randomised, controlled study. *Heart* 2009;95:1983-9 [19833610]

BOOST (Meyer), 2004:

Meyer GP, Wollert KC, Lotz J, Steffens J, Lippolt P, Fichtner S, Hecker H, Schaefer A, Arseniev L, Hertenstein B, Ganser A, Drexler H Intracoronary bone marrow cell transfer after myocardial infarction: eighteen months' follow-up data from the randomized, controlled BOOST (BOne marrOw transfer to enhance ST-elevation infarct regeneration) trial. *Circulation* 2006;113:1287-94 [16520413] [10.1161/CIRCULATIONAHA.105.575118](https://doi.org/10.1161/CIRCULATIONAHA.105.575118)

Wollert KC, Meyer GP, Lotz J, Ringes-Lichtenberg S, Lippolt P, Breidenbach C, Fichtner S, Korte T, Hornig B, Messinger D, Arseniev L, Hertenstein B, Ganser A, Drexler H Intracoronary autologous bone-marrow cell transfer after myocardial infarction: the BOOST randomised controlled clinical trial. *Lancet* 2004;364:141-8 [15246726] [10.1016/S0140-6736\(04\)16626-9](https://doi.org/10.1016/S0140-6736(04)16626-9)

Meyer GP, Wollert KC, Lotz J, Pirr J, Rager U, Lippolt P, Hahn A, Fichtner S, Schaefer A, Arseniev L, Ganser A, Drexler H Intracoronary bone marrow cell transfer after myocardial infarction: 5-year follow-up from the randomized-controlled BOOST trial. *Eur Heart J* 2009;30:2978-84 [19773226]

Chen, 2004:

Chen SL, Fang WW, Ye F, Liu YH, Qian J, Shan SJ, Zhang JJ, Chunhua RZ, Liao LM, Lin S, Sun JP Effect on left ventricular function of intracoronary transplantation of autologous bone marrow mesenchymal stem cell in patients with acute myocardial infarction. *Am J Cardiol* 2004;94:92-5 [15219514]

Huang, 2006:

Huang RC, Yao K, Zou YZ, Ge L, Qian JY, Yang J, Yang S, Niu YH, Li YL, Zhang YQ, Zhang F, Xu SK, Zhang SH, Sun AJ, Ge JB [Long term follow-up on emergent intracoronary autologous bone marrow mononuclear cell transplantation for acute inferior-wall myocardial infarction] *Zhonghua Yi Xue Za Zhi* 2006;86:1107-10 [[16796836](#)]

Karpov, 2005:

Karpov RS, Popov SV, Markov VA, Suslova TE, Ryabov VV, Poponina YS, Krylov AL, Sazonova SV Autologous mononuclear bone marrow cells during reparative regeneration after acute myocardial infarction. *Bull Exp Biol Med* 2005;140:640-3 [[16758644](#)]

Li, 2007:

Li ZQ, Zhang M, Jing YZ, Zhang WW, Liu Y, Cui LJ, Yuan L, Liu XZ, Yu X, Hu TS The clinical study of autologous peripheral blood stem cell transplantation by intracoronary infusion in patients with acute myocardial infarction (AMI). *Int J Cardiol* 2007;115:52-6 [[16822566](#)] [10.1016/j.ijcard.2006.04.005](#)

MAGIC (cell infusion), 2004:

Kang HJ, Kim HS, Zhang SY, Park KW, Cho HJ, Koo BK, Kim YJ, Soo Lee D, Sohn DW, Han KS, Oh BH, Lee MM, Park YB Effects of intracoronary infusion of peripheral blood stem-cells mobilised with granulocyte-colony stimulating factor on left ventricular systolic function and restenosis after coronary stenting in myocardial infarction: the MAGIC cell randomised clinical trial. *Lancet* 2004;363:751-6 [[15016484](#)]

MAGIC Cell-3-DES (Kang), 2006:

Kang HJ, Lee HY, Na SH, Chang SA, Park KW, Kim HK, Kim SY, Chang HJ, Lee W, Kang WJ, Koo BK, Kim YJ, Lee DS, Sohn DW, Han KS, Oh BH, Park YB, Kim HS Differential effect of intracoronary infusion of mobilized peripheral blood stem cells by granulocyte colony-stimulating factor on left ventricular function and remodeling in patients with acute myocardial infarction versus old myocardial infarction: the MAGIC Cell-3-DES randomized, controlled trial. *Circulation* 2006;114:1145-51 [[16820564](#)] [10.1161/CIRCULATIONAHA.105.001107](#)

Meluzin HD, 2006:

Meluzin J, Mayer J, Groch L, Janousek S, Horncek I, Hlinomaz O, Kala P, Panovsk R, Prsek J, Kamnek M, Stancek J, Klabusay M, Korstek Z, Navrtil M, Dusek L, Vinklrkov J Autologous transplantation of mononuclear bone marrow cells in patients with acute myocardial infarction: the effect of the dose of transplanted cells on myocardial function. *Am Heart J* 2006;152:975.e9-15 [[17070173](#)] [10.1016/j.ahj.2006.08.004](#)

Meluzin LD, 2006:

Meluzin J, Mayer J, Groch L, Janousek S, Horncek I, Hlinomaz O, Kala P, Panovsk R, Prsek J, Kamnek M, Stancek J, Klabusay M, Korstek Z, Navrtil M, Dusek L, Vinklrkov J Autologous transplantation of mononuclear bone marrow cells in patients with acute myocardial infarction: the effect of the dose of transplanted cells on myocardial function. *Am Heart J* 2006;152:975.e9-15 [[17070173](#)] [10.1016/j.ahj.2006.08.004](#)

Meluzin J, Janousek S, Mayer J, Groch L, Horncek I, Hlinomaz O, Kala P, Panovsk R, Prsek J, Kamnek M, Stancek J, Klabusay M, Korstek Z, Navrtil M, Dusek L, Vinklrkov J Three-, 6-, and 12-month results of autologous transplantation of mononuclear bone marrow cells in patients with acute myocardial infarction. *Int J Cardiol* 2008;128:185-92 [[17764767](#)]

Penicka, 2007:

Penicka M, Horak J, Kobyłka P, Pytlik R, Kozak T, Belohlavek O, Lang O, Skalicka H, Simek S, Palecek T, Linhart A, Aschermann M, Widimsky P Intracoronary injection of autologous bone marrow-derived mononuclear cells in patients with large anterior acute myocardial infarction: a prematurely terminated randomized study. *J Am Coll Cardiol* 2007;49:2373-4 [[17572255](#)] [10.1016/j.jacc.2007.04.009](#)

Ruan, 2005:

Ruan W, Pan CZ, Huang GQ, Li YL, Ge JB, Shu XH Assessment of left ventricular segmental function after autologous bone marrow stem cells transplantation in patients with acute myocardial infarction by tissue tracking and strain imaging. *Chin Med J (Engl)* 2005;118:1175-81 [[16117862](#)]

Suarez de Lezo (cell), 2007:

Suarez de Lezo J, Herrera C, Pan M, Romero M, Pavlovic D, Segura J, Sanchez J, Ojeda S, Torres A Rev Esp Cardiol 2007;60:357-65 [[17521544](#)]

TCT-STAMI (Ge), 2006:

Ge J, Li Y, Qian J, Shi J, Wang Q, Niu Y, Fan B, Liu X, Zhang S, Sun A, Zou Y Efficacy of emergent transcatheter transplantation of stem cells for treatment of acute myocardial infarction (TCT-STAMI). Heart 2006;92:1764-7 [[16775089](#)] [10.1136/hrt.2005.085431](#)

Janssens, 2006:

Janssens S, Dubois C, Bogaert J, Theunissen K, Deroose C, Desmet W, Kalantzi M, Herbots L, Sinnaeve P, Dens J, Maertens J, Rademakers F, Dymarkowski S, Gheysens O, Van Cleemput J, Bormans G, Nuyts J, Belmans A, Mortelmans L, Boogaerts M, Van de Werf F Autologous bone marrow-derived stem-cell transfer in patients with ST-segment elevation myocardial infarction: double-blind, randomised controlled trial. Lancet 2006;367:113-21 [[16413875](#)] [10.1016/S0140-6736\(05\)67861-0](#)

REPAIR-AMI (Schachinger), 2006:

Schachinger V, Erbs S, Elssser A, Haberbosch W, Hambrecht R, Hlschermann H, Yu J, Corti R, Mathey DG, Hamm CW, Sselbeck T, Assmus B, Tonn T, Dimmeler S, Zeiher AM Intracoronary bone marrow-derived progenitor cells in acute myocardial infarction. N Engl J Med 2006;355:1210-21 [[16990384](#)] [10.1056/NEJMoa060186](#)

Schachinger V, Erbs S, Elssser A, Haberbosch W, Hambrecht R, Hlschermann H, Yu J, Corti R, Mathey DG, Hamm CW, Sselbeck T, Werner N, Haase J, Neuzner J, Germing A, Mark B, Assmus B, Tonn T, Dimmeler S, Zeiher AM Improved clinical outcome after intracoronary administration of bone-marrow-derived progenitor cells in acute myocardial infarction: final 1-year results of the REPAIR-AMI trial. Eur Heart J 2006 Dec;27:2775-83 [[17098754](#)] [10.1093/eurheartj/ehl388](#)

Schachinger V, Assmus B, Erbs S, Elssser A, Haberbosch W, Hambrecht R, Yu J, Corti R, Mathey DG, Hamm CW, Tonn T, Dimmeler S, Zeiher AM Intracoronary infusion of bone marrow-derived mononuclear cells abrogates adverse left ventricular remodelling post-acute myocardial infarction: insights from the reinfusion of enriched progenitor cells and infarct remodelling in acute myocardial infarction (REPAIR-AMI) trial. Eur J Heart Fail 2009;11:973-9 [[19789401](#)]

TIME, :

ongoing trial

Traverse JH, Henry TD, Vaughn DE, Ellis SG, Pepine CJ, Willerson JT, Zhao DX, Piller LB, Penn MS, Byrne BJ, Perin EC, Gee AP, Hatzopoulos AK, McKenna DH, Forder JR, Taylor DA, Cogle CR, Olson RE, Jorgenson BC, Sayre SL, Vojvodic RW, Gordon DJ, Skarlatos S Rationale and design for TIME: A phase II, randomized, double-blind, placebo-controlled pilot trial evaluating the safety and effect of timing of administration of bone marrow mononuclear cells after acute myocardial infarction. Am Heart J 2009 Sep;158:356-63 [[19699857](#)] [10.1016/j.ahj.2009.06.009](#)